

NEXT PrEP: Novel Exploration of Therapeutics for PrEP

What is HPTN 069/ACTG 5305?

NEXT-PrEP, [Novel Exploration of Therapeutics (NEXT) for Pre-Exposure Prophylaxis (PrEP)], also known as the HPTN 069/ACTG 5305 study, is an HIV prevention study that is being done to learn more about the safety and acceptability of four different drug combinations when used as PrEP by men who have sex with men and women. PrEP is a new HIV prevention method in which people who are HIV-negative take HIV treatment drugs (antiretrovirals – ARVs) daily to reduce their risk of becoming HIV-infected. All of the drugs used in the study are approved by the Food and Drug Administration (FDA) to treat people with HIV infection. The drugs in this study are called maraviroc (also called Selzentry or MVC), emtricitabine (also called Emtriva or FTC), and tenofovir (also called Viread or TDF).

NEXT-PrEP is funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health (NIH). The study is a collaboration between the HIV Prevention Trials Network (HPTN) and the AIDS Clinical Trials Group (ACTG). Gilead Sciences and ViiV Healthcare are donating the study drugs.

How does PrEP work?

The idea behind PrEP is that if an HIV-negative person takes certain ARV pills on a regular schedule before they are exposed to HIV through sex, they may be protected from getting HIV infection. At least seven PrEP studies have either recently been completed or are underway in 13 countries involving more than 20,000 people with diverse HIV risk behaviors. All of these studies used one or two drugs as PrEP, either TDF (Viread) or the combination drug TDF/emtricitabine (FTC), called Truvada®.



Truvada: File Photo

In 2010, a study called iPrEx showed that daily use of Truvada® pills reduced the risk of HIV infection by 44 percent in HIV-negative men who have sex with men. Some of the men in the iPrEX study took the drugs more regularly; these men seem to have been even less likely to get infected with HIV. In 2011, two other studies also showed that Truvada® was effective in reducing HIV infection among heterosexual men and women. Based on all of these studies, in mid-2012, the FDA approved Truvada® to be used for prevention of HIV. This is the first ARV already approved for the treatment of HIV also to be approved for the prevention of HIV in adults.

These findings are encouraging, but additional studies are needed to see if other ARVs are safe or better tolerated and might be better at preventing HIV infection.

Where is the NEXT-PrEP study taking place and who is participating?



NEXT-PrEP will enroll a total of 600 HIV-negative people in 13 cities in the U.S. and Puerto Rico: Baltimore, MD; Boston, MA; Chapel Hill, NC; Cleveland, OH; Los Angeles, CA; Newark, NJ; New York City, NY; Philadelphia, PA; Pittsburgh, PA; San Francisco, CA; San Juan, PR; Seattle, WA; and Washington, DC.

The study is currently enrolling men, women and transgender individuals aged 18 and older who have sex with men. HIV infection rates are highest among young men aged 18 to 25, as well as people of color of all ages. As a result, the study will strive to enroll participants from these populations.

For a complete list of locations enrolling people into this study, visit the NEXT-PrEP study website at <http://www.NEXTPrEPStudy.org>.

Why is the NEXT-PrEP study important?

The NEXT-PrEP study is an important next step in helping to determine if future research should be done to see if different ARVs can be used as PrEP. There are some concerns about the possibility of side effects and resistance related to the ARVs that are currently used for PrEP. Resistance means that some strains of HIV can no longer be treated with certain ARVs. Maraviroc is an approved drug that blocks entry of HIV into cells. It has been shown to be safe for use by HIV-positive people and rarely causes drug resistance. This will be the first study to see if maraviroc is safe and tolerable when used by HIV-negative people as an HIV prevention strategy. The results of the NEXT-PrEP study will help researchers decide if maraviroc should be tested further to see if it prevents new HIV infections when it is used as PrEP.

How will the study work?

NEXT-PrEP will help us to understand the safety and tolerability of the drugs being used in the study. HIV-negative people will take one of four different combinations of ARV drugs. Each person will be randomly assigned (like pulling numbers out of a hat) to one of the four groups. All participants will take three pills every day. Each group will receive at least one active drug in their set of three daily pills. All of the pills, including those which are inactive (called placebos) will look exactly like the real pills. The researchers and participants will not know which group people are in or which drugs the participants are taking. This is because the researchers do not want to have any influence on how the results of the study will come out. The groups look like this:

- One group will get maraviroc + placebo pill + placebo pill
- One group will get maraviroc + FTC + placebo pill
- One group will get maraviroc + TDF + placebo pill
- One group will get TDF + FTC + placebo pill

All study participants will be observed to see if they experience any side effects. Though it is not expected, if there are any serious side effects reported for any of the groups, individuals in that group will be told to stop taking the drugs.

In addition to taking the PrEP regimens, participants will be told that one of the best things they can do to protect themselves from getting HIV and other sexually transmitted infections (like gonorrhea, syphilis or chlamydia) is to use a condom every time they have sex.

Participants will be in the study for about one year, and will meet with members of their local study team about 10 times over the course of that year. At these visits the study team will provide a physical exam, check the health of their liver, bones and kidneys, and discuss any concerns or side effects that may be related to the study drugs. All participants will receive HIV prevention counseling, and an HIV test and condoms at each study visit.

Where is more information about the NEXT-PrEP study available?

For additional information about the NEXT-PrEP study visit www.NEXTPrEP.org, or follow HPTN on Facebook and Twitter at HIVpnt. For information on other HPTN studies visit www.HPTN.org.

